

Answers to Questions 1

FY 2015-2016 Funding Opportunity Announcement (FOA)

James and Esther King Biomedical Research Program (King) Bankhead-Coley Cancer Research Program (Bankhead-Coley)

- Can a PI apply for both Discovery Science and Bridge grant?
 Eligible applicants can submit one application to the Bankhead-Coley program, and one application to the King program. Applications must be different. Applicants may not submit the same applications, or substantially similar applications as determined by the Department, to both the King and Bankhead-Coley programs.
- 2. What is maximal requested amount allowed for a Technology Transfer Feasibility (TTF) grant? Can a TTF grant proposal be submitted separately or only within indicated Grant Mechanisms (Discovery Science, Research Infrastructure, Clinical Research, and Bridge)?
 - This Funding Opportunity Announcement does not include a separate mechanism for TTF. Technology transfer is a research priority, and projects must fall under one of the mechanisms of support provided in this call. The potential award amount is defined under these mechanisms.
- 3. I am interested in submitting an application for the above program that is specific to gastric cancer. I noticed that the focus is on tobacco-related cancers, which gastric cancer is but when the cancers are specified only lung, breast, prostate, colon and melanoma are specified. Is a proposal in gastric cancer appropriate for the James King program?
 - Grant applications must be responsive to one of the research priorities listed in this Funding Opportunity Announcement. If the researcher selects a priority which lists specific cancers, the application must be responsive to one of the cancers listed (lung cancer, breast cancer, prostate cancer, colon cancer, and melanoma).
- 4. Our currently research project is about smoking induced neuropathic pain and the mechanism. We already have some preliminary data and would like to apply grant from your department. Can you please let us know if our project is in your funding priority? Grant applications must be responsive to one of the research priorities listed in this Funding Opportunity Announcement.
- 5. Last year I submitted an Idea Development Award proposal to the Department of Defense Lung Cancer Research Program and received a Peer Review Summary Statement with an Average Score of 1.9 (Excellent), S.D. 0.1. The scores range from 1.0 (highest merit) to 5.0 (lowest merit). However, no percentile scores are provided. Would an average score of 1.9 meet the requirements for the bridge award submission?

When the federal mechanism reports a score but does not provide a percentile ranking, applicants should contact their federal funding agency and request a percentile ranking if possible. Reviewers will consider scores in the absence of an available percentile ranking.

6. It was stated in the Bridge grant that "The applicant must have received a peer review summary statement indicating high scientific merit. For purposes of this competition, "high scientific merit" is a percentile ranking of 16th or better". However some NIH R grant mechanisms don't have percentile rankings. In some cases applicants only receive the impact scores in the summary statements. For example, NCI's pay line for the R03 proposals is 25 (impact scores). Can we apply for a bridge grant if we received 30 (impact score)?

See answer to question 5.

- 7. Can we submit a project in pancreatic cancer for discovery science? See the answer to question 3.
- 8. DoD grant applications are scored with an overall impact score but not ranked by percentile. What impact score would qualify a DoD application for a bridge grant? See answer to question 5.
- 9. I am considering submitting an LOI to the Bankhead-Coley Cancer Research Program this year. Would my application be considered eligible if portions of it were also part of an R01 application that is currently under review at NIH? Yes, you would be eligible to apply to the Bankhead-Coley or King Program while your application is under review at NIH. You would be ineligible to receive funding from the Bankhead-Coley or King Program if you were to receive NIH funding for the same application.
- 10. Question A: Does Research Priority 8 (IND-IDE, page 6) allow for a 2-phase project to include:
 - 1) prototyping a biomedical device used for treating a specific cardiovascular event and 2) an associated IDE for validating the prototype in humans (animal models are unsuitable in this case)?

If the answer to Question A is "yes," is Clinical Research the correct Mechanism of Support for both phases collectively? If the answer to Question A is "no," might part 1 (prototyping) qualify for Research Priority 7 (Technology Transfer Feasibility, page 5)? Yes, if the project is tobacco-related and the phases requested can be accomplished within the funding period (3 years for Discovery Science and Research Infrastructure and 5 years for Clinical Research).

The Department cannot advise a Principal Investigator on the appropriate mechanism of support to select for their project. Principal Investigator's should select a mechanism of support that will best fit the aims of their project based on the mechanisms of support descriptions listed in the FOA.

11. What is the page limit for the Research/Project Plan to be submitted via the online system?

The online application will prompt applicants of required fields and word limits for each section. The online application system will be open to receive applications on the date listed in Table 1 of the FOA.

- 12. We do not see references listed in Table 2 components. Are reference citations to be included as an Appendix within the Research/Project Plan? If not, where will they be included? Do they count toward any page limit?
 - Appendixes are not allowed. The online application includes a section titled "Bibliography and Reference Cited", where references can be cited.
- 13. We are planning to apply for the Bankhead-Coley Cancer Research Program grant and would like to know if Multiple PI mechanisms is allowed.

There needs to be one designated Principal Investigator. Additional researchers would be listed at Co-Principal Investigators. There can be multiple collaborators on a project, but there must be only one Principal Investigator.

14. Am I eligible based on Canadian Citizenship?

The Principal Investigator must be a U.S. citizen or permanent resident; unauthorized aliens shall not be employed pursuant to §274A(e) of the Immigration and Naturalization Act (8 U.S.C. 1324a), section 101 of the Immigration Reform and Control Act of 1986, and Florida Executive Order 11-02.

- 15. Can I submit a pancreatic cancer project in Clinical Research category? See answer to question 3.
- 16. Does the grant cover research in other tobacco-related disorders other than cancer, such as neurodegenerative disorders?
 See answer to question 3.
- 17. I applied for Bankhead-Coley funding last cycle but did not receive it. I got the critiques back and would like to revise my application and resubmit. Would this be submitted as a new application and new LOI or is there a mechanism for a re-application with response to reviewers?

This would be considered a revised application and a Letter of Intent is required to be eligible. When completing a Letter of Intent in the online system, you will have the option to select that the application is a revised application that was submitted but not funded during the FY 2014-15 competition. There is no specific mechanism for a re-application with response to reviewers.

18. The overview for the James and Esther King Biomedical Research Program states that the purpose of the Program "is to support research initiatives that address the health care problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke and pulmonary disease...." However, the Research Priorities listed appear to be limited to cancer and cancer-treatment related morbidities in other systems. Is this correct – the Program will only accept proposals that are related to cancer or cancer.

All applications must be responsive to one of the research priorities listed within the funding opportunity. The priorities listed in this funding opportunity were developed by the BRAC based on the Strategic Goals and Tactics developed in 2014. Priorities for this current FOA (see priorities 1-8) are targeted and include prevention and treatment of specific tobacco-related cancers, health disparities issues related to specific tobacco-related cancers, screening, tobacco use, obesity research, and treatment of cancer related morbidities in other systems such as the reproductive system. Based upon recommendations from the Biomedical Research Advisory Council, future Funding Opportunity Announcements may focus on other priorities.

- 19. If we have a subcontractor who will use the 15% indirect cost rate on their portion of the budget, is the applicant allowed to take 15% indirect on the entire subcontract budget (direct and indirect) or only on their direct cost portion? Additional indirect costs by subcontractors are not allowed in excess of the allowable amount based on the total cost of the grant.
- 20. Can a University submit multiple proposals as long as they are different Principal Investigators?
 Each organization can submit one infrastructure grant to the Bankhead-Coley and one to King as the lead organization. There is no limit to the total number of grant proposals an organization can submit for the Clinical Trial, Discovery Science, or Bridge mechanisms. However, Principal Investigators at organizations are limited to one application for Bankhead-Coley and one application for King.
- 21. Can you please clarify whether there is a limit on the number of applications an eligible organization can submit to the James and Esther King Biomedical Research Program and Bankhead-Coley Cancer Research Program? It appears there is a one lead application limit on Infrastructure Grants but there does not appear to be any listed limits on the other categories.
 See the answer to Question 20.
- 22. Can a PI apply with a clinical research proposal in which we aim to reduce the mortality of head and neck cancer patients with a combinational immunotherapeutic treatment for the James and Esther King Biomedical Research Program?

 See answer to question 3.